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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,694	08/07/2001	Atsushi Suzuki	210377US0	8724

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
HAWES, PILI ASABI	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,694	SUZUKI ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 40-70 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11-02-2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 11-02-2005 is acknowledged. Claims 40-70 are pending in this action. Claims 40-70 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-02-2005 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54, 55, 57, 58, 64, 65, 67, and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54, 55, 57, 58, 64, 65, 67, and 68 recite the limitation "wherein the systolic [or diastolic] pressure is reduced" in the first line of the claim. Claim 53, 63, and 66 do not refer to the systolic or diastolic pressure. Thus, there is insufficient antecedent basis for this limitation in the claim. It is suggested the claims 53, 63, and 66 be

amended to include the terms systolic and diastolic pressure so that there will be sufficient antecedent basis for the dependent claims.

Double Patenting

Claims 40-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,310,100 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose treatments for hypertension comprised of ferulic acid or a derivative thereof. The therapeutic compositions comprising ferulic acid and its derivatives may further comprise pharmaceutical products, nutritional supplements or products, and foods. The reference does not specifically claim chlorogenic or caffeic acid in combination with ferulic acid, but in claim 5 it does disclose a composition "consisting essentially of ferulic acid or a derivative thereof, and at least one other anti-hypertensive compound," which would encompass chlorogenic and caffeic acid. One of ordinary skill in the art would be motivated to combine chlorogenic and caffeic acids, which are known anti-hypertensive agents to a composition comprising ferulic acid with the expectation of successful treatment of hypertension with such a composition.

Claims 40-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 11/209672. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are directed to an agent for preventing, improving or treating hypertension the agent consists of caffeic

acid, chlorogenic, and ferulic acid and a component that stimulated the central nervous system. Although the instant claims do not include a component the stimulates the central nervous system, it would be obvious to use compounds such as sugar alcohols because not only do they stimulate the central nervous system, but they improve the taste of the oral composition. One of ordinary skill in the art would be motivated to combine the chlorogenic, caffeic acid, and ferulic acid in a composition for treating hypertension because the combination would most likely have additive effects, if not synergistic effects in treating hypertension.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46-52, 56-65 are rejected under 35 U.S.C 103(a) as being unpatentable over Abraham (XP-001148404, 1996) in view of Hsu (US 5,958,417) and further in view of Ghai et al. (US 5,955,269). The claims are to a food supplemented with ferulic acid and caffeic acid, chlorogenic acid or a combination of caffeic acid and chlorogenic acid. Abraham discloses a dietary constituent comprising a combination of chlorogenic acid, caffeic acid and ferulic acid (Table 1). These phenolic compounds occur in some of the commonly consumed vegetables, fruits and beverages (page 19, column 1). Abraham does not expressly disclose that the referenced dietary constituents are used in the treatment of hypertension. However, Hsu ('417) addresses this limitation by disclosing that the active principles, chlorogenic acid and caffeic acid, found in the herbal substance, Crataegus, are used to treat hypertension (column 2, lines 59-61).

One of ordinary skill in the art would have been motivated to combine the dietary constituents disclosed by Abraham to make a composition for treatment of hypertension as discussed by Hsu because of the need for alternatives to conventional pharmaceuticals currently used to treat hypertension, with an expectation of fewer harmful side effects.

The examiner cites Ghai et al. (US 5, 955,269) that discloses processed foods, or foods fortified with nutraceuticals and the methods of adjusting the combination and level of these nutraceutical compounds in a supplement or in food products to achieve

added nutritional or therapeutic benefit (col. 25, lines 1-3, col. 26, lines 43-50 and col. 27, lines 19-25). The reference further teaches that nutraceutical compounds can be administered by inhalation; orally as tablets, capsules, or liquid preparations; controlled release formulations; or as food supplements (col. 25-26). Table 1 (col. 23, lines 41-65) further discloses examples of phenolic acids, such as caffeic, chlorogenic, and ferulic acids as examples of food substances that can be used as nutraceuticals. The reference does not disclose the anti-hypertensive properties of caffeic, chlorogenic, or ferulic acids. However, the teachings of Hsu, as discussed above, do address this limitation. It would have been obvious to one of ordinary skill in the art to combine ferulic acid with chlorogenic acid and caffeic acid as taught by Ghai to obtain synergistic effects in the treatment of hypertension. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a nutraceutical supplement to fortify foods or beverages as taught by Ghai, and to use said foods or beverages in the treatment of hypertension as taught by Hsu, with an expectation of reduced toxicity.

Note: the previous rejection is sustained for the food claims because the language "consisting of" is not being used, thus the claim is interpreted to mean comprising and thus the references cited in the previous office action still read on the instant claims. If the language "consisting of" was used to define the supplement consisting of isolated or purified ferulic acid, caffeic acid and/or chlorogenic, then the claims would be free of the cited prior art, and thus would be allowable.

Allowable Subject Matter

Claims 40-45, 53, 66, 69, and 70 are allowable with the filing of a terminal disclaimer.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

The following is a statement of reasons for the indication of allowable subject matter: The amendment of the instant claims from "consisting essentially of" to "consisting of" sufficiently defines the invention so that it is free of the prior art. The closest prior art reference is US 2002/0187239, which discloses a nutritional supplement added to food products that comprises caffeic acid, chlorogenic acid, and ferulic acid. However the reference does not teach using a mixture of all three. The reference is not prior art because of the foreign priority date 08-07-2000 of the instant application is prior to the filing date of the PG-Pub.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER